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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,739	04/30/2001	George Jackowski	2132.044	3449

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EXAMINER	
COOK, LISA V	
ART UNIT	**PAPER NUMBER**
1641	16

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,739	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1,2,10-17 and 29-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-9,18-28 and 33-35* is/are rejected.

7)☒ Claim(s) *3-9,18-28 and 33-35* is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 April 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7&14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 3-9, 18-28, and 33-35) in Paper No. 13 filed 2/5/03 is acknowledged. Applicant traverses the instant Restriction under *Ochiai* and further points to the office rejoining in related application no. 09/846,352 a prior to Allowance. Examiner acknowledges the *In re Ochiai* practice and will rejoin once allowable subject matter is determined.

> In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and In re Brouwer, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product. In both cases, the Federal Circuit held that the use of per se rules is improper in applying the test for obviousness under 35 U.S.C. 103. Rather, 35 U.S.C. 103 requires a highly fact-dependent analysis involving taking the claimed subject matter as a whole and comparing it to the prior art. To support a rejection under 35 U.S.C. 103, the collective teachings of the prior art must have suggested to one of ordinary skill in the art that, at the time the invention was made, applicant's claimed invention would have been obvious. In applying this test to the claims on appeal in Ochiai and Brouwer, the court held that there simply was no suggestion or motivation in the prior art to make or use novel, nonobvious products in the claimed processes. Consequently, the court overturned the rejections based upon 35 U.S.C. 103

The Restriction Requirement is deemed proper and is therefore made **FINAL.**

2. Claims 1-2, 10-17, and 29-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Currently claims 3-9, 18-28, and 33-35 are under consideration.

Priority

3. The instant application does not claim priority or benefits to an earlier application.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

5. The information disclosure statements filed 2/11/02 in paper #7 and filed 12/9/02 in paper #14 have been considered as to the merits prior to first action.

Drawings

6. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. The drawings in this application are objected to by the Examiner under 37 CFR 1.821(a)(1) and (a)(2) because the graph contains a sequence, which has not been identified appropriately. The sequence must include a sequence identification number. Please submit new formal drawings including the seq. id. no. Specifically SEQ ID NO:1.

Sequence Non-Compliance

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. The disclosure contains sequences that have not been appropriately identified by sequence identification numbers, see page 27 for example. SKITHRIHWESASLL should be accompanied with SEQ ID NO:1.

Applicant is given THREE MONTS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Specification

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. On page 6 line 13 a typo appears. A ")" is missing. Please add.

II. The use of the trademarks has been noted in this application. (.i.e. Sepharose on page 22 line 21, Amicon on page 27 line 8). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

III. The Abstract is Objection because the instant application utilizes the legal phraseology "said". Appropriate correction is required.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

IV. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. See page 33 lines 3-8. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Objections

9. Claims 3-9, 18-28, and 33-35 are objected to because of the following informalities: Claims 1 and 2 are identified as "Claim 1 and Claim 2", however the claims should be identified as " 1 and 2." Therein conforming to the same format as the other claims in the application. A single format should be consistently utilized for clarity. Appropriate correction is required.

10. Claims 3-9, 18-28, and 33-35 are objected to because of the following informalities: The claims refer to the biopolymer of claim 1. Although acceptable the claims would be clearer, if they were written to include SEQ ID NO:1. This would eliminate ambiguity, when claims are canceled, amended, etc during prosecution. Please add SEQ ID NO:1 to the independent claims 3, 18, 33, 34, and 35.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 3-9, 18-28, and 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Regarding claims 4 and 5, the phrase "particularly" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

B. In claims 3-5 the terms "evidencing" and "characterizing" are vague and indefinite because it is not clear as to what "evidencing" and "characterizing" encompasses. If the method merely detects congestive heart failure via a biopolymer marker as (defined in the disclosure) it is suggested that the phrases are replaced with "detecting" in order to clarify applicant's intended meaning.

C. Claim 7 is not recited in the proper Markush format. Therein it in not clear as to what "at least one of the group consisting of" refers. It is suggested that "at least one" be replaced with "selected from the group consisting of" for clarity.

D. Claims 3-9, 18-28, and 33-35 are vague and indefinite because it is unclear as to what the term "at least one analyte thereof" is intended to define. The claim is directed to an antibody that binds a biopolymer SEQ ID NO 1. However what is considered an analyte of SEQ ID NO 1 is not defined by the claims or the specification. As recited the metes and bounds of the claims cannot be determined and one of ordinary skill in the art would not be appraised of the scope of the instant invention. Please explain.

E. Claims 18, 25, and 33-35 are vague and indefinite in utilizing the phrase "including". Although the phrase has defined meaning it is not clearly defined in the composition/biopolymer of the instant application. Is it applicants' intent to mean that the biopolymer is the sequence identified as SEQ ID NO:1. It is suggested that the claims recite "consisting of" to clarify the composition. The claims are further unclear because "SEQ ID NO:1 has not been set forth in the claims. Please add.

F. The term "regulation" in claim 35 is a relative term, which renders the claim indefinite. The term "regulation" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to how the measurement of the biopolymer marker will further serve to control the absence and/or presence of the aforementioned biopolymer or an analyte thereof. It is suggested that the claim merely recite detection of the biopolymer.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 3-9, 18-28, and 33-35 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well-established utility.

Claims 3-9, 18-28, and 33-35 are broadly drawn to methods of determining the presence or absence of a biopolymer marker having SEQ ID NO:1 as an indicator of at least one disease state (specification only sets forth congestive heart failure). These diagnostic methods include for example biopolymer evidencing, characterization, regulation, risk-assessment, and therapeutic identification. The specification also contemplates the use of these methods for diagnosing, staging, monitoring, prognosticating or determining predisposition to the at least one disease state (specification only sets forth congestive heart failure).

Applicants have disclosed in the specification that SEQ ID NO: 1 is measurable in patients with congestive heart failure. See figure 1. The specification also states that the said sequence was highly expressed in congestive heart failure, but undetectable in other tested disease related to Syndrome X, such as overt diabetes and kidney failure. See page 16, lines 9-18 and page 26 line 20 through page 27 lines 2. This is contradictory to information presented in the prior art regarding the utility of the same sequence, namely SEQ ID NO:1. U.S. Patent #5,849,297, U.S. Patent #6,221,657, and U.S. Patent 36,268,485 teaches utility in myocardial ischemia, frostbite, burns, (column 7 lines 28-29); glomerulonehritis, haemolytic anemia, myasthenia gravis, and type II collagen induced arthritis (column 7 lines 34-35). These results do not support Applicants' asserted use of the claimed methods for detection of any disorder, particularly congestive heart failure. There are no disclosure or working examples that demonstrate the specifically asserted utility and evidences a substantial utility was well established at the time of filing. Further it is not clear how the same biopolymer marker will be utilized to distinguish various unrelated disease states. If the marker is measurable in various disease states how will it distinguish the disease states. It is not clear how one will assess the particular disease state. In other word will the patient have myocardial ischemia, frostbite, burns, glomerulonehritis, haemolytic anemia, myasthenia gravis, type II collagen induced arthritis, or congestive heart failure. The specification does not enable one of ordinary skill in the art to definitively assess the incidence or further distinguish between both diseases in a single test sample.

And while the evidence presented in the specification does point to the high occurrence of the sequence in congestive heart failure, this is not sufficient in implementing the said sequences in a molecular based diagnostic method for at least one disease state with the said sequence. Furthermore, Applicants have not provided any disclosure enabling the use of the biopolymer marker with regard to regulating the presence or absence of said sequence. There is no disclosure designating how the sequence bound in the method that could be regarded as enabling one of ordinary skill in the art to use the said sequences in the diagnostic method.

Applicants have not set forth any supporting evidence that suggests that any of the sequences (SEQ ID NO: 1) are unique molecular markers for congestive heart failure. Based on the analysis set forth above the specification does not exemplify sufficient findings that constitute a specific, substantial or credible utility.

Claims 3-9, 18-28, and 33-35 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial or credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 3-9, 18-28, and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 3-9, 18-28, and 33-35 are broadly drawn to methods of determining the presence or absence of at least one disease state (specification only sets forth congestive heart failure) by analyzing a biological sample obtained from a patient to identify the biopolymer marker sequence consisting of sequence identification NO:1. The specification also contemplates the use of these methods for diagnosing, staging, monitoring, prognosticating or determining predisposition to at least one disease state (specification only sets forth congestive heart failure).

These diagnostic methods include for example biopolymer evidencing, characterization, regulation, risk-assessment, and therapeutic identification. The specification asserts that the said target sequence was found in at least one disease state (specification only sets forth congestive heart failure). However, the obtained results set forth in the specification for example in figure 1 is not clearly indicative of at least one disease state (specification only sets forth congestive heart failure), because no control sample analysis is presented by way of example.

Further it is not clear how the same biopolymer marker will be utilized to distinguish any disease state, other than congestive heart failure because no other disease states were analyzed with the marker as a positive indicator of such disease state. In other words how will one identify any other disease state with the biopolymer having SEQ ID NO:1 when no such data has been presented. The specification does not enable one of ordinary skill in the art to definitively assess the incidence or further distinguish between any and all diseases other than congestive heart failure in a single test sample. And while the evidence presented in the specification does point to the high occurrence of the sequence in congestive heart failure, this is not sufficient in implementing the said sequences in a molecular based diagnostic method for congestive heart failure and any other disease state with said sequence. Furthermore, Applicants have not provided any disclosure enabling the use of the biopolymer marker with regard to regulating the presence or absence of said sequence. There is no disclosure designating how the sequence bound in the method that could be regarded as enabling one of ordinary skill in the art to use the said sequences in the diagnostic method.

Applicants have not set forth any supporting evidence that suggests that any of the sequences (SEQ ID NO: 1) are unique molecular markers for congestive heart failure and all other possible disease states. Tascilar et al. (Annals of Oncology 10,Suppl. 4:S107-S110, 1999) reports on diagnostic methods in the realm of disease states, however this review article is relevant to Applicants' claimed invention. It is art known that molecular–based assays are valid tools used in predicting and detecting diseases, however as assessed in the Tascilar review "...these tests should be interpreted with caution...". and "the genetic changes found in sources other than the pancreas itself (blood, stool) should be evaluated prudently".

Furthermore, Tockman et al. (Cancer Research 52:2711s-2718s, 1992) teach considerations necessary for a suspected cancer biomarker (intermediate end point marker) to have efficacy and success in a clinical application. Although the reference is drawn to biomarkers for early lung cancer detection, the basic principles taught are clearly applicable to other oncogenic disorders. Tockman teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials, see abstract. Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and **if validated** (emphasis added) can be used for population screening (p. 2713s, column 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome.

The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease. "This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point [marker]", see page 2714s, column 1, Biomarker Validation against Acknowledged Disease End Points section. Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials, see page 2716s, column 2, Summary section. Tockman reiterates that the predictability of the art in regards to cancer prognosis and the estimation of life expectancies within a population with a disease or disorder are highly speculative and unpredictable.

Based on the analysis and the teachings presented above it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims and to practice the invention as claimed.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

I. Claims 3-9, 18-28, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrison et al. (US Patent #5,849,297).

Harrison et al. disclose biologically active polypeptides comprising therapeutically active polypeptides. See abstract. Applicants sequence identification number 1 is disclosed as sequence identification number 1 in the patent to Harrison et al. Therein the claimed sequence is taught. Harrison et al. further teach the utility of said sequences in disease state detection, evaluation, and treatment. See column 6 through column 8.

II. Claims 3-9, 18-28, and 33-35 are rejected under 35 U.S.C. 102(a)(e) as being anticipated by Harrison et al.(US Patent #6,221,657).

Harrison et al. disclose biologically active polypeptides comprising therapeutically active polypeptides. See abstract. Applicants sequence identification number 1 is disclosed as sequence identification number 1 in the patent to Harrison et al. Therein the claimed sequence is taught. Harrison et al. further teach the utility of said sequences in disease state detection, evaluation, and treatment. See column 6 through column 8.

III. Claims 3-9, 18-28, and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Farries et al. (US Patent #6,268,485).

Farries et al. disclose native pathway proteins, which form a down-regulation resistant C3 convertase. The proteins are modified human C3 protein. Applicants sequence identification number 1 is disclosed as sequence identification number 22 in the patent to Ferries et al. Therein the claimed sequence is taught. Ferries et al. further teach the utility of said sequences in disease state detection, evaluation, and treatment. See column 6 through column 8.

13. For reasons aforementioned, no claims are allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook
CM1-7B17
(703) 305-0808
4/2/03

LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/06/03